Pursued RSV

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office
M2501N

60 8th Street, N.E.
Atlanta, Georgia 30309

March 30, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

George White, Owner
White Shrimp Company
103 West Cedar Road
Frogmore, SC 29920

Warning Letter
(99-ATL-16)

Dear Mr. White:

On February 9 & 10, 1999, the Food and Drug Administration (FDA) conducted an inspection of your plant located at Shipman Dock Road, Frogmore, South Carolina. The investigators documented deviations from FDA's seafood processing regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123), causing the seafood products processed by your firm, including histamine-forming species and fresh shrimp, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), as follows:

1. Monitoring records are missing and/or incomplete [21 CFR 123.9(c) and 123.6(c)(7)]. Specifically, monitoring records required by your HACCP plans for histamine-forming fish species and fresh shrimp were not available for review during the inspection. For example, your *RECEIVING, REFRIGERATED STORAGE & CORRECTIVE ACTION FORM* contained entries for only three days for the receipt and storage of histamine susceptible fish even though your firm receives and processes weekly shipments of such fish. There were no monitoring records documenting cooler temperatures from July 14, 1998 to October 14, 1998. In addition, there were no production records available documenting the time the fish is exposed to unrefrigerated conditions during the filleting operation, and the adequacy of the ice coverage during the shipping operation. With regard to your shrimp operation, you have failed to complete the *SHRIMP DOCK RECEIVING/LABEL CHECK & CORRECTIVE ACTION RECORD* for each incoming lot of fresh shrimp as required by your HACCP plan.

2. Failure to calibrate process-monitoring instruments in accordance with 21 CFR 123.8(a)(2). Specifically, the thermometers used for checking internal fish

temperatures, and storage cooler temperatures had apparently never been calibrated until our January 1999 inspection.

3. Failure to specify an appropriate critical limit for the receiving step in your HACCP plan for histamine susceptible species [21 CFR 123.6(c)(3)]. Specifically, this critical control point (CCP) is missing a critical limit for the internal temperature of the incoming fish. It appears that part of this critical limit has been erroneously placed under the *Monitoring What* column of your plan. In addition, the *Monitoring How* column appears to contain the information that should be placed under the *Monitoring What* column for the receiving step.

The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA will not issue any certificates of export for any of the seafood products processed at your facility until your firm is fully in compliance with the seafood HACCP regulation.

Please notify this office, in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your written reply should be directed to Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309.

Sincerely,

for Roger E. Kline

Ballard H. Graham, Director
Atlanta District